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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,989	11/06/2001	Jaime Simon	61350A	5337

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THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/036,989

Applicant(s)

SIMON ET AL.

Examin r

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120.

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of Applicant's amendment, filed on May 9, 2003, is acknowledged.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0077956.

The patent discloses microcapsules obtained by incorporating a water-swellaable polymer into the core material and incorporating an enteric polymeric material in the coating, and capable of releasing the core material in the intestinal tract (See p. 2, lines 3-24). The patent includes phthalic acid esters of hydroxyalkyl alkylcellulose or cellulose acetate among the enteric polymers used in the invention (See p. 4, lines 4-19). The patent teaches that the water-swellaable polymer shows at least 1.2 times increase in weight when immersed in water and includes polysaccharides, copolymers of divinylbenzene and acrylic acid, and crosslinked polyacrylic acid among the water-swellaable polymers encompassed by the invention (See p. 5, line 22 to p. 6, line 9). The patent teaches that the core comprising the water-swellaable polymer is in the form of granule.

The compositions disclosed by the patent meet the limitations of claims 19-27 of the instant application, as they contemplate compositions comprising enterically coated water-absorbing polymers. Thus, the patent anticipates the claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2 and 4-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imondi et al. (U.S. Patent 4,143,130) in view of Hider et al. (U.S. Patent 6,132,706).

Imondi et al. provides water-soluble carboxylic acid polymers promoting phosphate absorption and having a swelling index of 10-1500 for the treatment of kidney stones (See col. 1, line 1 to col. 3, line 47). Imondi et al. teaches that the compositions of the invention may be formulated in enterically coated capsules, as claimed in claims 14 and 17 of the instant application, and the formulations may contain combinations of drugs suited to the treatment of kidney stones and relief of pain (See col. 4, lines 1-6).

Thus, Imondi et al. provides a method for the treatment of kidney diseases comprising administering swellable polymers to a patient in enterically coated oral formulations and compositions comprising said polymers. With respect to the limitation in claims 1, 2 and 4-27, that the polymer is capable of absorbing physiological saline, the patent teaches that the polymers of the invention have a swelling index of 10-1500 (See col. 3, lines 42-47). The carboxylic acid polymers disclosed by the prior art include acrylic acid monomers, as claimed in claims 7, 8, 23 and 24 of the application (See col. 2, line 10 to col. 3, line 41). With regard to

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claims 10-12, Imondi et al. teaches that the polymers of the invention bind calcium, reduce urinary calcium load and absorb phosphate (See col. 1, lines 32-62). With respect to the enteric coating claimed in claims 13 and 15 of the application, the patent contemplates enterically coated dosage forms, and the polymers claimed by Applicant are routinely used in the art for enteric coating formulations. With respect to the bead form claimed in claim 27, the polyacrylic acid produced in Example 12 is a white brittle solid.

Imondi et al. is deficient in the sense, that the patent does not specifically teach that the polymers of the invention are used for removing fluid from the intestinal tract or for treating fluid overload states, as claimed in claims 1 and 16 of the instant application, and does not teach a polysaccharide, as claimed in claims 9 and 25, or a crosslinked polyallylamine, as claimed in claim 26.

Hider et al. teaches that kidney dialysis patients suffer from elevated serum level of phosphate, and patients who possess inefficient kidneys frequently develop kidney stones (See col. 1, lines 15-20). The patent provides pharmaceutical compositions comprising crosslinked polymers comprising polyacrylic acid derived polymers and teaches that the preferred route of administration is orally, with the polymers remaining in the intestine and not absorbed into the patient's bloodstream (See col. 2, lines 21-57). Hider et al. teaches that carbohydrate polymers (polysaccharides) are particularly advantageous (See col. 2, lines 58-65). In Example 2, a polyallylguanidinium chloride resin is disclosed.

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Thus, Heller et al. teaches that kidney dialysis patients and those who possess kidney insufficiency develop kidney stones.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the method and compositions disclosed by Imondi et al. to treating kidney diseases related to kidney insufficiency, such as fluid removal from the intestinal tract, due to renal insufficiency, as claimed in the instant composition. The expected result would have been a successful composition and successful methods of treatment. Because of the teachings of Imondi et al., that compositions and formulations comprising the polymers of the invention are effective in treating kidney stones, and the teachings of Hider et al., that patients with renal insufficiency frequently develop kidney stones, one of ordinary skill in the art would have a reasonable expectation that the methods and compositions claimed in the instant application would be successful in removing water excess from the intestine. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

5. Applicant's arguments filed May 9, 2003 have been fully considered but they have been found only partially persuasive.

6. Applicant's argument with respect to the 35 U.S.C. 102(b) rejection of claims 1 and 16 over Berger et al. has been found persuasive in view of Applicant's amendment, since gastric

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administration interferes with the capability of the polymer to absorb physiological saline, as claimed in the instant application. Accordingly, said rejection is withdrawn.

7. Applicant's argument with respect to the 35 U.S.C. 102(b) rejection of claims 1 and 16 over Polycarbophil has been found persuasive in view of Applicant's amendment, since Polycarbophil does not absorb physiological saline in the amounts claimed in the instant application. Accordingly, said rejection is withdrawn.

8. In response to Applicant's argument, that Samejima et al. does not teach or suggest that the active material is the polymer itself, it is noted that claims 19-27 of the instant application read on a composition comprising a polymer. The patent discloses microcapsules comprising a water-swellaable polymer, thus the prior art provides compositions comprising a polymer as claimed by Applicant.

9. Applicant's argument with respect to Watts and Berger et al. have been found persuasive in view of Applicant's amendment, since the gastric administration disclosed by Berger et al. interferes with the capability of the polymer to absorb physiological saline, as claimed in the instant application, and the water in the capsules disclosed by Watts would render the polymer incapable of absorbing fluid in the intestinal tract. However, the teachings of Imondi et al. are still considered relevant in view of Applicant's amendment, since the prior art provides water-soluble carboxylic acid polymers promoting phosphate absorption and having a swelling index of 10-1500 for the treatment of kidney diseases (See rejection above).

Conclusion

10. Claims 1, 2 and 4-27 are rejected.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Sen83

June 17, 2003

Thurman K. Page
THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600